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## A 2-year community-randomized controlled trial of fluoride varnish to prevent early childhood caries in Aboriginal children.

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#### Abstract

**OBJECTIVE:** To measure the effectiveness of fluoride varnish (FV) (Duraflor), 5% sodium fluoride, Pharmascience Inc., Montréal, QC, Canada) and caregiver counseling in preventing early childhood caries (ECC) in Aboriginal children in a 2-year community-randomized controlled trial.

**METHODS:** Twenty First Nations communities in the Sioux Lookout Zone (SLZ), Northwest Ontario, Canada were randomized to two study groups. All caregivers received oral health counseling, while children in one group received FV twice per year and the controls received no varnish. A total of 1275, 6 months to 5-year-old children from the SLZ communities were enrolled. In addition, a convenience sample of 150 primarily non-Aboriginal children of the same age were recruited from the neighboring community of Thunder Bay and used as comparisons. Longitudinal examinations for the dmft/s indices were conducted by calibrated hygienists in 2003, 2004 and 2005.

**RESULTS:** Aboriginal children living in the SLZ or in Thunder Bay had significantly higher caries prevalence and severity than non-Aboriginal children in Thunder Bay. FV treatment conferred an 18% reduction in the 2-year mean 'net' dmfs increment for Aboriginal children and a 25% reduction for all children, using cluster analysis to adjust for the intra-cluster correlation among children in the same community. Adjusted odds ratio for caries incidence was 1.96 times higher in the controls than in the FV group (95% CI = 1.08-3.56; P = 0.027). For those caries-free at baseline, the number (of children) needed to treat (NNT) equaled 7.4.

**CONCLUSIONS:** Findings support the use of FV at least twice per year, in conjunction with caregiver counseling, to prevent ECC, reduce caries increment and oral health inequalities between young Aboriginal and non-Aboriginal children.

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